K101676

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

SEP 13 2010

Sybron Dental Specialties, Inc.
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Wendy Garman - Contact Person

Date Summary Prepared: June 2010

Device Name:

- Trade Name – ClearArch
- Common Name – Orthodontic Wire
- Classification Name – Orthodontic Appliance and Accessories, per 21 CFR § 872.5410

Devices for Which Substantial Equivalence is Claimed:

- BioMers Products, LLC, *BioMers Translucent Orthodontic Wire*

Device Description:

ClearArch is a polymer-based orthodontic archwire for maxillary and mandibular arches. The wire material 1) is more aesthetic than conventional metal wires, 2) can take different shapes, including round, rectangular and square cross-sections, 3) can be bent like TMA and 4) delivers orthodontic forces similar to nickel titanium archwires. This archwire is intended to be used during the first two phases of orthodontic treatment. Its stiffness and strength are similar to the properties of metal orthodontic archwires in order to aid in efficient tooth movement during orthodontic treatment. Therefore, orthodontists can use an esthetic archwire in lieu of a less esthetic metal version without compromising treatment mechanics.

Intended Use of the Device:

The ClearArch is indicated for use as an orthodontic archwire to aid in the movement of patient teeth during orthodontic treatment. ClearArch is intended for patients seeking esthetic orthodontic treatment; these are primarily patients being treated with ceramic or polycarbonate braces.

Substantial Equivalence:

The ClearArch wire is substantially equivalent to one other legally marketed device in the United States. ClearArch functions in a manner similar to and is intended for the same use as the BioMers Translucent Orthodontic Wire which is currently being marketed by BioMers Products LLC. The ClearArch wire differs from the predicate device only in composition, in that, the ClearArch wire is polymer-based while the BioMers Translucent Orthodontic Wire, also polymer-based (BIS-EMA and TEGDMA), has additional glass fibers. Biocompatibility studies have been completed, which demonstrates that the material used to produce ClearArch is safe for its intended use.

The 510(k) submission also includes data from bench testing used to evaluate the performance characteristics of ClearArch compared to the predicate device, BioMers Translucent Orthodontic Wire. The characteristics evaluated include flexural strength, tensile strength, friction, water absorption and elongation of standardized comparative samples.

Based upon the biocompatibility tests and bench testing, the clinical performance of ClearArch is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

SEP 13 2010

Re: K101676
Trade/Device Name: ClearArch
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Codes: DYW
Dated: June 14, 2010
Received: June 15, 2010

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101676

Device Name: *ClearArch*

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Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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